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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,643	11/02/2000	Vojin Jeremijevic	Q61622	8866

7590

04/08/2003

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EXAMINER

GHAFOORIAN, ROZ

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 04/08/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,643

Applicant(s)

JEREMIJEVIC, VOJIN

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 15-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-22 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 23-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3, 26-29, 30-32, and 36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent 4790828 to Dombrowski et al.

Dombrowski discloses a self-capping needle assembly. It contains a sleeve with a through bore 45 defined on a given axis, a first link 58 having a first and second ends, a hinge means 50 for connection the first end of the link 58 to the sleeve 28, a base means 12 suitable for receiving the base end of the needle to be protected, a crank arm 56, the crank arm being no greater than the length of the link. It further contains a second link and crank arm. The first and second links and crank arm are situated substantially in a common plane and form substantially a quadrilateral whose diagonal are substantially perpendicular. (Figs 1-5) The device is capable of having multiple positions, a "starting position" figure 2, a "in use position" which would be the position between figures 2 and 3, and a "locked position" figure 3.

2. Claims 15-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5743888 to Wilkes et al.

Wilkes disclose a safely needle. Wilkes's apparatus contains a sleeve having a through bore a base secured to the base end of the needle and link means connecting the sleeve to the base, with 2 channels and shutter, the shutter being suitable for taking up a first position and a second position. (Figures 5-7) It further contains a flexible rod and a release cavity; means for locking the position of the second end of the flexible rod end

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it is retracted into the second channel portion (figures 8a-8g). The first part and second part formed on either side of the through bore the first part of the first channel portion being in line with the second channel portion. The rod the shutter is made as a single piece, of a plastic material. Wilkes also comprises of a first link 67 and a first crank arm 67, the first link having a first and second end, a resilient return hinge 69 for connecting the first end of the first link to the sleeve 15, said hinge means being organized so that said first link takes up a defined equilibrium position figure 4c on a direction that makes an acute angle with the axis of the through bore.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent 4790828 to Dombrowski et al., and further in view of U.S Patent No.5197954 to Cameron.

As mentioned above Dombrowski discloses a self-capping needle assembly. Dombrowski, does not disclose a base with two part attached via a weak point. However the idea of a mechanism that allows the caregiver to modify the syringe by breaking a part of the syringe is not new in the art and Cameron is only one example. Cameron teaches a hypodermic syringe having folding needle. Cameron's syringe

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contains a base with two parts allowing the caregiver to break the needle away once it has been used.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined these two studies because according to Cameron the ability to break the needle away safely eliminated the problems of re-use and accidental injury from used hypodermic syringes. (Col.1, lines 35-40)

4. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent 4790828 to Dombrowski et al, and further in view of U.S Patent No.4283493 to Schlesinger.

As mentioned above Dombrowski discloses a self-capping needle assembly.

Dombrowski, however, does not disclose a sachet made of non-stretch material and being capable of tearing under a given traction. Schlesinger teaches a biological specimen collection and transport system.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined these two studies because according to Schlesinger the sachet is simple to use and enhances prevention of the spread of infection during transportation and analysis of the collected specimen. (Col. 1, lines 65-67)

Response to Arguments

5. Applicant's arguments filed 7-30-02 have been fully considered but they are not persuasive.

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- a. the applicant alleges the hing 50 in Dombrowski is not resilient, however the definition of resilient in the dictionary is "ability to adjust easily" and hing 50 must be able to adjust easily when sleeve 36 is moving from first position in figure 2 to second position in figure 3, if hing 50 was not able to adjust easily when sleeve moved it would lead to separation of hing 50 and sleeve 36. furthermore Dombrowski does teach several positions, one position is when the needle bevel is exposed (fig 2) the second position is when the needle bevel is covered (fig 3) and the 3rd position is in between fig 2 and fig 3 when sleeve is in route to cover the needle bevel. applicant accuses the examiner of not examining the structure close enough to see the difference between the prior art and the applicant's invention, however that is false Dombrowski's apparatus might not use the same names the applicant has selected to use in his invention however Dombrowski's invention consists of same structures that perform the same function the applicant's invention is performing. therefore rejection regarding claims 1-14, 22-36 are deemed proper and are hence maintained.
- b. the applicant further alleges the addition of the word "equilibrium" to claim 1 will overcome the prior art Dombrowski. However the word equilibrium means "state of balance between opposite forces" and Dombrowski is capable of having both positions starting and in use in equilibrium.

Allowable Subject Matter

6. Newly amended Claims 15-22 in Paper No.5 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The applicant has claimed a syringe with a cover sleeve containing a first channel portion with a shutter slidably mounted in the first channel where the shutter is suitable for taking up a first and second shutter position, this shutter sleeve system is in combination with a resilient link system which allows the sleeve to move in three different positions. It is the combination of the shutter sleeve system and the resilient link system, which makes claims 15-22 allowable. The close prior art are US Patent No.4790828 to Dombrowski et al, US Patent No.5304151 to Kuracina, and US Patent No.6443929 to Kuracina. Neither of the prior art mentioned above teach a syringe assembly with a resilient link system (which allows for three different position) with a first channel is the sleeve with a shutter system slidably mounted inside the first channel where the first channel is intersecting the though bore in a portion lying between its second outlet and the sharp end of the needle when the sleeve is in the first sleeve position.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

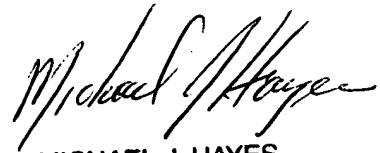
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to be 'RG' followed by a stylized flourish.

RG
April 2, 2003

A handwritten signature in black ink, reading 'Michael J. Hayes' in a cursive style.

MICHAEL J. HAYES
PRIMARY EXAMINER